UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

CHILDREN'S HOSPITAL OF THE KING'S DAUGHTERS, INCORPORATED

Plaintiff,

v.

THOMAS E. PRICE, in his official capacity, Secretary, Department of Health and Human Services; PATRICK CONWAY, in his official capacity, Acting Administrator, Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

Case No.: 2:17-cv-00139-RBS-LRL

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR EMERGENCY INJUNCTIVE RELIEF

Plaintiff Children's Hospital of The King's Daughters, Incorporated ("CHKD") is at immediate risk of having to repay, in as little as one month's time, $19.1 million in supplemental Medicaid funding received in 2013 that Congress mandated that hospitals like CHKD receive because of its disproportionately large Medicaid population. It has also been denied an estimated $8.1 million it expected to receive in 2017. The loss of these funds directly impacts CHKD's ability to address unmet public health needs in and around its community. Thus, CHKD moves to preliminarily enjoin, as two other federal district courts have done,[1] implementation and enforcement of a Medicaid Disproportionate Share Hospital Program ("DSH") auditing and reporting guideline issued by Defendant Centers for Medicare and Medicaid Services ("CMS")

[1] In addition, the U.S District Court for the District of Minnesota entered an agreed upon order that provides that CMS would not enforce, apply, or implement FAQ 33 in Minnesota pending a decision on the merits in that case. *Children's Health Care v. Burwell*, Case No. 16-cv-4064, ECF No. 30 (D.Minn. Jan. 4, 2017), at 2.

which is the source of Plaintiff's irreparable injury. The challenged guideline substantively modifies the existing regulations in violation of the Administrative Procedure Act ("APA") and is contrary to Congress's unambiguous purpose in enacting the DSH Program. This guidance, that only appears on CMS's website, is titled "Additional Information on the DSH Reporting and Audit Requirements," hereinafter "FAQ 33." As set forth below, Plaintiff meets each of the factors that entitle it to a preliminary injunction.

INTRODUCTION

On March 3, 2017, the United States District Court for the District of New Hampshire, permanently enjoined CMS from enforcing FAQ 33 in New Hampshire "until and unless [its] policies and procedures are replaced by an enforceable and properly promulgated regulation." *N.H. Hosp. Ass'n v. Burwell*, No. 1:15-cv-00460, ECF No. 51 (D.N.H. March 2, 2017), attached as Exhibit 1 to the Declaration of Stephen Noona ("Exhibit 1"), at 47. In December 2014, the United States District Court for the District of Columbia preliminarily enjoined CMS from "enforcing, applying, or implementing" FAQ 33, holding that plaintiffs were likely to succeed in showing that FAQ 33 "makes a substantive change to the formula for calculating a hospital's DSH limit, binds state Medicaid agencies, and effectively amends the 2008 Rule" without following the APA's procedural requirements. *Texas Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 241 (D.D.C. 2014).[2] FAQ 33 unlawfully requires that payments hospitals receive from "private insurance," wholly unrelated to the Medicaid program, be included in the calculation that determines the maximum amount of Medicaid DSH funds a DSH hospital may receive.[3]

[2] Judgment on the merits is pending in the *Texas Children's Hosp.* case.
[3] "Private insurance" means health plan coverage provided through an employer or union, or purchased by an individual from a commercial health insurance company. Revenues received from private insurers are considered third party revenues.

Despite the courts' rulings, CMS maintains that FAQ 33 is a "policy clarification" that is applicable in all states where the courts have not intervened. Because CMS continues to enforce FAQ 33 in Virginia, CHKD, a not-for-profit hospital dedicated to the treatment and special needs of children, received notice that it must repay by March 29, 2017, $19.1 million in DSH funds it rightfully received and relied upon in 2013. In addition, CHKD has been notified that it will not receive approximately $8.1 million in DSH funds it expected to receive for 2017. Thus, CHKD is facing the imminent and irreparable loss of over $27.2 million in DSH funding that Congress mandated DSH hospitals, like CHKD, receive. Once taken, CHKD has no legal recourse to recover the funds. The loss of DSH funds significantly harms CHKD's ability to continue to address current and unmet public health needs in and around its community, including, but not limited to, investments by CHKD necessary to (1) expand its urgent care center locations that provide needed care at times when children would otherwise have to seek care from emergency rooms or go without care; (2) become a Level 1 pediatric trauma center; (3) strengthen its cardiac surgery program; (4) address the region's desperate shortage of quality mental health services for youth; and (5) build and expand facilities on CHKD's main campus and throughout the community to allow for better access to care exclusively dedicated to children and provided only by CHKD in its region.

The DSH Program was created by Congress to ensure that hospitals that serve a disproportionate number of Medicaid and other low income patients with special needs obtain additional governmental assistance to survive the financial consequences of treating patients whom other providers view as financially undesirable. Congress recognized that these hospitals do not have sufficient resources to make up the significant losses inured treating Medicaid patients. CHKD's Medicaid population in 2013 was over 71%, which is significantly higher

than any other general hospital in Virginia. Yet CMS's unlawful actions strip CHKD of DSH funds Congress intended it receive, severely harming CHKD's ability to achieve and maintain its mission-driven programs and services.

Accordingly, CHKD seeks an order enjoining Defendants from enforcing, applying, or implementing FAQ 33 or its policy in Virginia and directing Defendants to notify the Virginia Department of Medical Assistance Services ("DMAS") that, pending further order by the Court, CMS is enjoined from FAQ 33 and its policy are enjoined enforcing, applying, or implementing FAQ 33 or its policy in Virginia and that any overpayments previously identified for recoupment resulting from application of FAQ 33 are not considered overpayments subject for recoupment.

STATUTORY AND REGULATORY BACKGROUND

The Medicaid Program

Established in 1965, the Medicaid program (Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.*, also referred to as the "Medicaid Act") "is a cooperative federal-state public assistance program that makes federal funds available to states electing to furnish medical services to certain impoverished individuals." *Mowbray v. Kozlowski*, 914 F.2d 593, 595 (4th Cir. 1990); *see also Harris v. McRae*, 448 U.S. 297, 301 (1980). State participation in the Medicaid program is voluntary; however, a state that participates must comply with "'detailed federally mandated standards.'" *Three Lower Ctys. Cmty. Health Servs., Inc. v. Maryland,* 498 F.3d 294, 297 (4th Cir. 2007) (quoting *Antrican v. Odom,* 290 F.3d 178, 183 n. 2 (4th Cir.2002)).

Each state administers its own Medicaid program pursuant to a state Medicaid plan which must be reviewed and approved by the Secretary of Health and Human Services.[4] *See* 42 U.S.C. § 1396a(a). Once the plan is approved, the federal government subsidizes the state's medical-

[4] The Secretary has delegated this authority to CMS.

assistance services by providing federal matching funds (the "federal financial participation" or "FFP"). *Id.* § 1396b(a)(1). DMAS administers the Medicaid program in Virginia.

Congress gave states "substantial discretion to choose the proper mix of amount, scope, and duration limitations" of their Medicaid programs. *Alexander v. Choate*, 469 U.S. 287, 303 (1985). However, if a state fails to comply with federal requirements, including CMS guidance, it will lose its federal funds. 42 U.S.C. §§ 1396a(a)(1)-(65), 1396(c).

The Disproportionate Share Hospital Program

In 1981, Congress required that all states participating in the Medicaid program establish a DSH Program to provide "payment adjustments" to hospitals that serve large numbers of Medicaid and other low-income patients with special needs ("DSH payments"). *See* Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97–35, § 2173(B)(ii), 95 Stat. 357 (codified at 42 U.S.C. § 1396a(13)(A)(iv); 42 U.S.C. § 1396r-4(c)). Congress's intent "was to stabilize the hospitals financially and preserve access to health care services for eligible low-income patients." *Texas Children's Hosp.*, 76 F. Supp. 3d at 230 (internal quotation marks omitted). The Medicaid Act specifically provides that hospitals are "deemed" to be DSH hospitals entitled to receive DSH payments if "the hospital's Medicaid inpatient utilization rate … is at least one standard deviation above the mean Medicaid inpatient utilization rate for hospitals receiving Medicaid payments in the State."[5] 42 U.S.C. § 1396r-4(b)(1)(A).

A DSH payment adjustment cannot exceed a hospital's "hospital-specific limit" ("HSL"). *See* 42 U.S.C. § 1396r-4(g). More specifically, a hospital's annual DSH payment may not exceed a hospital's "uncompensated costs" of serving Medicaid and uninsured patients. 42 U.S.C. § 1396r-4(g)(1)(A). Uncompensated costs are defined as:

[5] A hospital is also deemed to be a DSH Hospital if it has a low-income utilization rate that exceeds 25 percent. 42 U.S.C. § 1396r-4(b).

> [T]he *costs* incurred during the year *of furnishing hospital services* (as determined by the Secretary and *net of payments under this subchapter*, other than under this section, and by uninsured patients) by the hospital *to individuals who* either *are eligible for medical assistance under the State plan* or have no health insurance (or other source of third party coverage) for services provided during the year.

Id. (emphases added). Thus, a DSH hospital's total uncompensated costs are made up of two components: (1) the costs of hospital services to individuals eligible for Medicaid, net of payments under the Medicaid Act (the "Medicaid shortfall"); and (2) the costs of hospital services to individuals who have no health insurance or other third-party coverage, net of payments by those uninsured patients (the uninsured component). Only the method of calculating the Medicaid shortfall is at issue in this case. The statutory formula for calculating the Medicaid shortfall can be expressed as:

Medicaid Allowable Costs for All Eligible Patients	–	Medicaid Payments	=	Medicaid shortfall component of HSL

In 2003, Congress enacted section 1001 of the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066, to require states to submit annual reports and independent certified audits to CMS on their DSH Programs. The reports must identify each hospital to which the state has made DSH payments and the audit must verify that the state's DSH payments comply with the statutory requirements. Pub. L. No. 108-173, § 1001(d) (codified at 42 U.S.C. § 1396r-4(j)(2)(C), (D)). If the audit finds that DSH payments received exceed a hospital's HSL, the state must recoup these "overpayments" within one year of their discovery or lose the federal financial share. *See id.* § 1396b(d)(2)(C), (D).

The CMS Regulations

On December 19, 2008, CMS promulgated a final regulation implementing the DSH reporting and auditing requirements. 73 Fed. Reg. 77,904, 77,950 (the "2008 Rule"). The 2008 Rule requires states to submit information "for each DSH hospital to which the State made a

DSH payment." 42 C.F.R. § 447.299(c). The 2008 Rule further requires each hospital to report its "total annual uncompensated care costs" and sets forth the regulatory formula for determining such costs by specifically defining each type of cost and payment to be included in the calculation. 42 C.F.R. § 447.299(c)(16). Private health insurance payments are not included in the regulatory formula.

The auditing provisions of the rule require participating states to submit annual DSH Program audits that include a CMS-approved auditor's "determination of whether or not the State made DSH payments that exceeded any hospital's specific DSH limit" in the audit year. 42 C.F.R § 455.301. The 2011 DSH year (subject to audit in 2014) was the first year in which CMS required states to recoup overpayments or face "the return of the Federal share to the Federal government." 73 Fed. Reg. at 77,906.

FAQ 33

Despite the unambiguous language of the statute and regulations, on January 10, 2010, CMS required, for the first time, that revenues from "private insurance" be included in the calculation of the Medicaid shortfall component of the HSL. Without notice or opportunity for comment, CMS posted on its website answers to questions regarding the reporting and audit requirements, which included FAQ 33. The question posed in FAQ 33 was:

> Would days, costs, and revenues associated with patients that have both Medicaid and private insurance coverage (such as Blue Cross) also be included in the calculation of the MIUR percentage and the DSH limit in the same way States include days, costs and revenues associated with individuals dually eligible for Medicaid and Medicare?

In response CMS stated:

> Days, cost, and revenues associated with patients that are dually eligible for Medicaid and private insurance should be included in the calculation of the Medicaid inpatient utilization rate (MIUR) for the purposes of determining a hospital eligible to receive DSH Payments. Section 1923(g)(1) does not contain an exclusion for individuals eligible for Medicaid and also enrolled in private

> health insurance. *Therefore, days, costs, and revenues associated with patients that are eligible for Medicaid and also have private insurance should be included in the calculation of the hospital-specific DSH limit. As Medicaid should be the payer of last resort, hospitals should also offset both Medicaid and third-party revenue associated with the Medicaid eligible day against the costs for that day to determine any uncompensated amount*.[6]

(Emphasis added). Thus, for the first time, CMS directed states to include in the calculation of the Medicaid shortfall component of the HSL revenues received from "private insurance" even though claims had not been submitted to the Medicaid program for payment, nor had Medicaid paid for any portion of the inpatient or outpatient hospital services for which private insurance revenues were received. As a result, revenues that exceed Medicaid allowable costs and revenues for services not covered by the Medicaid program are offset against the Medicaid costs incurred for patients for whom Medicaid was the primary payer. This artificially decreases the HSL and deprives DSH hospitals, like CHKD, of DSH funding it needs to continue to provide the full range of services to the community and is otherwise entitled to receive.

The *Texas Children's Hospital and New Hampshire Hospital Association* Litigations

Following the issuance of a preliminary injunction in March 2016 and a hearing on the merits on March 2, 2017, the United States District Court for the District of New Hampshire (McCafferty, J.) permanently enjoined CMS from enforcing FAQ 33,[7] holding that CMS acted in excess of its statutory authority because the statute does not authorize CMS to "define the phrase 'costs incurred' in FAQs." Exhibit 1 at 35. Similarly, on December 29, 2014, the United States District Court for the District of Columbia (Sullivan, J.) held that Texas Children's Hospital and

[6] FAQ 33 is *available at* https://www.medicaid.gov/medicaid/financing-and-reimbursement/downloads/part-1-additional-info-on-dsh-reporting-and-auditing.pdf, last visited on March 6, 2017.

[7] The court also enjoined CMS's enforcement of FAQ 34, which directs that payments received under the Medicare Program, which is distinct from the Medicaid Program, are to be included in the calculation of the hospital specific limit for calculating DSH payments. Thus, like FAQ 33, FAQ 34 applies payments from outside the Medicaid Program to the DSH Program. FAQ 34 is not at issue here because children are, generally, not eligible to receive Medicare.

Seattle Children's Hospital were likely to succeed on the merits of their claim that the policy contained in FAQ 33, requiring the inclusion of private health insurance payments in the calculation of the Medicaid Shortfall component of the DSH HSL, is illegal and void. *Texas Children's*, 76 F. Supp. 3d at 241. The court found that: (1) the policy articulated in FAQ 33 is not codified in either the statute or the 2008 Rule and therefore had "independent legal effect;" and (2) FAQ 33 was not promulgated through notice-and-comment rulemaking in violation of the APA. *Id.* at 238, 241.

In issuing preliminary injunctions, both courts held that the plaintiffs would suffer imminent irreparable harm if CMS were not enjoined from enforcing its unauthorized policies. As Judge Sullivan found, "Plaintiffs' harms are 'certain' because the state agencies must recoup the alleged overpayments within one year of discovering them, or the federal government will recoup its share." *Id.* at 243 (citation omitted). And both courts found that the harm was irreparable because any monies recouped could not be recovered. *Id.* at 242; *N.H. Hosp. Ass'n v. Burwell*, 2016 WL 1048023, at *17-18 (D. N.H. Mar. 11, 2016). For these reasons, the courts enjoined CMS from "enforcing, applying, or implementing the policies referenced in FAQ[] 33." *Id.* at *19; *Texas Children's Hosp*., 76 F. Supp. 3d at 246-47 (granting motion for injunction preventing government "from enforcing, applying, or implementing FAQ No. 33").

STATEMENT OF FACTS

Children's Hospital of The King's Daughters

CHKD is an independent not-for-profit 206-bed children's hospital, with its main campus located in Norfolk, Virginia. Declaration of Dennis Ryan ("Ryan Decl.") ¶ 1. CHKD is Virginia's only freestanding, full-service children's hospital providing care to children from birth through age 21. *Id.* ¶ 2. For 120 years, CHKD has served children in southeastern Virginia and

northeastern North Carolina, but children from throughout the United States also come to CHKD because of its pediatric expertise. *Id.* ¶¶ 2-4.

CHKD's Pediatric Intensive Care Unit is the region's only civilian critical care facility for infants, children and adolescents suffering from acute, life-threatening illnesses and injuries. *Id.* ¶ 3. CHKD also operates the region's only level IV Neonatal Intensive Care Unit ("NICU") with 62 beds for the most critically ill newborns in the region, including infants transferred from military facilities and lower level specialty nurseries at other hospitals in Virginia. *Id.* CHKD offers the region's only pediatric emergency center, cancer and blood disorders program, child abuse program, inpatient rehabilitation unit and pediatric urgent care centers. *Id.* CHKD also operates the region's only pediatric surgery program, offering everything from pediatric outpatient procedures to the most complex neurosurgery, orthopedic and cardiac surgeries. *Id.* CHKD offers a full range of pediatric primary care and pediatric medical and surgical services (encompassing all subspecialties, including genetics, neurology, pulmonology, cardiology, nephrology, urology, gastroenterology, craniofacial surgery, psychiatry and many others) thereby providing the full continuum of pediatric care. *Id.* CHKD serves as the primary teaching hospital and the home for Eastern Virginia Medical School's Department of Pediatrics and its graduate residency training program in pediatrics. *Id.*

CHKD has the highest Medicaid Inpatient Utilization Rate ("MIUR") in Virginia. In 2012, CHKD's MIUR reported by DMAS to CMS was 69.65%. *Id.* ¶ 5. The Virginia general hospital with the second highest MIUR was only 41.99%. *Id.* In stark contrast, CHKD's patient population covered by commercial insurance averages 30%. *Id.* As a result, CHKD is more reliant on the Medicaid program than any other hospital in Virginia. *Id*. This is typically true of a children's hospital, as 1 in 3 children in this country are covered by Medicaid. *Id*. ¶¶ 5-6. In

addition, unlike adult hospitals, children's hospitals do not receive significant reimbursement from Medicare.[8] *Id*. ¶ 5.

Medicaid payments fall far short of reimbursing CHKD for the actual costs it incurs in treating Medicaid patients. *Id*. ¶ 7. Medicaid currently reimburses CHKD on average only $0.69 for every dollar spent to provide care to Medicaid patients. *Id.* As a result, CHKD sustains substantial financial losses from treating Medicaid patients. *Id.* ¶ 8. It is because of this financial loss that CHKD relies so heavily on the DSH Program to make up some of its financial shortfall suffered in treating such a disproportionately high number of Medicaid patients. *Id*. ¶¶ 8, 10-11. Yet even with DSH funds, CHKD sustains significant financial losses in its treatment of Medicaid patients. *Id.* ¶ 9. CMS's enforcement of FAQ 33 now threatens to eliminate CHKD's DSH funding altogether thereby severely harming CHKD and its pediatric community.

The Loss of DSH Funds Harms CHKD and Its Pediatric Community

The loss of DSH funding materially harms CHKD's mission-driven programs that provide essential clinical programs and medical services to the regional community. Ryan Decl. ¶¶ 29, 36, 38. For example, CHKD operates multidisciplinary outpatient facilities and health and surgery centers to be more accessible to all communities, including underserved populations in the region. *Id*. ¶ 36. To that end, CHKD is investing resources to increase access to care by expanding its urgent care center locations that provide needed care at times when children would otherwise have to seek care from emergency rooms or go without care. *Id*. It is also making the investments necessary to: qualify as a Level 1 pediatric trauma center; strengthen its cardiac surgery program; address the region's desperate shortage of quality mental health services for youth by recently establishing an outpatient behavioral health program; and build and expand

[8] The only children eligible to receive Medicare are those with end stage renal disease and certain disabilities and those children are a very small fraction of CHKD's patient population. Ryan Decl. ¶ 5.

new facilities on the main campus and throughout the community to allow for better access to care exclusively dedicated to children and provided only by CHKD in its region. *Id*. CHKD has committed funding to increase access to clinical services, preventive care and community outreach programs for children, including psychiatry, psychology and behavioral health programs and *Healthy You for Life*, CHKD's comprehensive program aimed at decreasing rates of childhood obesity. *Id*. CHKD's ability to continue investing in these services, including its ability to recruit and retain the pediatric primary care professionals and pediatric specialists essential to its patients, will be directly impacted by the loss of DSH funds. *Id*.

In addition, CHKD provides substantial funding to connect a sprawling community to providers, establishing services at distant locations and a telehealth program aimed at expanding access to high level pediatric care through a variety of technology-assisted means. *Id*. ¶ 37. Furthermore, CHKD recognizes its commitment to serving the most fragile and traumatized pediatric members of its community through the operation of a regional Child Abuse Program designed to accurately identify, treat and protect children who have been abused or neglected. *Id*. CHKD's Child Abuse Program partners with law enforcement, the legal system and the military in every city it serves to obtain the information, interviews and examinations necessary through a process that recognizes the level of trauma already experienced by children and their families. *Id*. The level of support services required to address the developmental, emotional, psychosocial, school and family resource needs of CHKD's patients is enormous. *Id*. CHKD employs and deploys a multidisciplinary team that includes physicians, nurses, allied health professionals, social workers, child life therapists, chaplains, educators, case managers, interpreters, dietitians, financial counselors, and patient advocates to care for the whole child and provide resources essential to achieving the best medical—and life—outcomes possible. *Id*.

Many of these support services are not sustainable absent support by CHKD and are at risk if CHKD is forced to repay DSH funds already received and relied upon and is denied current and future DSH funding. *Id*.

The DSH Audits

It was not until October 4, 2016, that CHKD became aware of the extent to which FAQ 33 would adversely impact CHKD. Ryan Decl. ¶ 23. Prior to that time, FAQ 33 had not materially impacted CHKD's HSL. *See id*. ¶ 17.

The audit of CHKD's 2011 DSH payment, conducted in 2014, identified an overpayment of $4.9 million, resulting principally from disallowance of certain transportation costs claimed. *Id.*¶ 15. The auditors did not identify any issues with CHKD's data that relied on the state's "MR report," which compiles the Medicaid claims data CHKD submits, *i.e*., costs and payments, including data for Medicaid-eligible children covered by private insurance. The auditors instruct CHKD to use to complete the DSH surveys, which the auditors then use to conduct audits. *Id.* ¶¶ 14-15. The auditors identified one account for a premature infant that was covered by private insurance that was not included in the MR report, to which they applied the full amount of the commercial insurance payments received. *Id.* ¶ 15. Thus, while CHKD became aware of FAQ 33 in 2014, it appeared to impact only one account and therefore did not appear to be a significant issue. *Id*. CHKD also understood that in December 2014, the *Texas Children's Hospital* court had enjoined CMS from applying FAQ 33. *Id*. In the audit of the 2012 DSH funds, the auditors did not identify any issues with CHKD's data derived from the MR report and did not identify any overpayments in its final audit results. *Id*. ¶ 16.

In early 2016, CHKD learned from DMAS that the *Texas Children's* injunction did not apply in Virginia and that CMS had instructed all other states to apply FAQ 33's policy in audits of 2013 DSH funds. *Id.* ¶ 18. Like it had done for the 2011 and 2012 audits, CHKD compiled

the data requested from the MR report, but also supplemented it to include the full amount of commercial third party payments received. *Id.* ¶ 19. It did so because it was unclear whether, in fact, the full payments were reflected in the MR report. *Id*. The auditors subsequently removed the supplemental data CHKD provided explaining that it was duplicative of information already contained in the MR report. *Id.* ¶ 21. The audit identified a $1.2 million overpayment. *Id.*

Because CHKD was confused as to how the auditors were accounting for commercial payments, CHKD qualified its audit certification to reflect its understanding that the auditors were offsetting the total amount of commercial payments CHKD received against CHKD's Medicaid allowable costs. *Id*. ¶ 22. On October 4, 2016, the auditors informed CHKD that they discovered that the MR report used for DSH audit purposes only included commercial insurance payments up to the amount of what the Medicaid program would have paid for these patients. *Id*. ¶ 23. The auditors further informed CHKD that because FAQ 33 requires the full amount of the commercial payments received to be included in the DSH audit, the preliminary audit determination was revised from identifying an "overpayment" of $1.2 million to an "overpayment" of $19,167,660. *Id*. By letter dated February 23, 2017, CHKD was notified that the audit determination was final and that CHKD had 33 days to submit payment.[9] *Id*. ¶ 24.

[9] The letter also advises CHKD that it could appeal the decision in accordance with Virginia administrative regulations governing provider appeals. *See* Ryan Decl., Exhibit 9, at 2 (appeals are governed by 12VAC30-20-500 through 560). However, 12VAC30-20-520 provides that "[a] provider may not appeal the actual payment methodologies." Moreover, federal law establishes the methodology used to determine the HSL and FAQ 33 is a federal policy that CMS requires Virginia to follow. *See* Ryan Decl., Exhibit 2 (email from DMAS informing CHKD that CMS has instructed states to apply FAQ 33 and stating that DMAS will continue to apply FAQ 33). Thus, even if DMAS concluded that this issue was appealable under Virginia law, the state administrative process cannot provide CHKD relief and does not diminish the imminent harm caused by the imminent recoupment. *See, e.g*., *Masterman v. Goodno*, No. Civ. 03-2939, 2004 WL 51271, at *13 (D. Minn. Jan. 8, 2004) (finding irreparable harm when the state Medicaid administrative appeal process would not provide adequate protection from the threatened harm and "counsel for the defendant could not assure the Court that plaintiffs would not be faced with

STANDARD OF REVIEW

When considering a preliminary injunction, a court "'must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.'" *Winter v. Natural Res. Defense Council*, 555 U.S. 7, 24 (2008) (quoting *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 542 (1987)). A court "should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Id*. (internal quotations omitted). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter*, 555 U.S. at 24; *accord United States v. South Carolina*, 720 F.3d 518, 533 (4th Cir. 2013); *Real Truth About Obama, Inc. v. Fed. Election Comm'n,* 575 F.3d 342, 346 (4th Cir. 2009), *vacated on other grounds*, 559 U.S. 1089 (2010).

ARGUMENT

I. CHKD IS LIKELY TO SUCCEED ON THE MERITS OF ITS CLAIMS

CHKD alleges two violations of law against Defendants' issuance and enforcement of FAQ 33: (1) Defendants violated the APA by issuing a legislative rule that substantively modifies the existing regulations without observance of procedure required by law (Complaint ¶¶ 101-109); and (2) Defendants violated the APA by acting in excess of their statutory jurisdiction, their statutory authority, and short of statutory right under the Medicaid Act (Complaint ¶¶ 9-100). CHKD is likely to succeed on both of these claims.

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recoupment"). Even if the state administrative appeals process delayed recoupment, that would not invalidate FAQ 33 or preclude injunctive relief. *See N.J. Hosp. Ass'n v. Waldman*, 73 F.3d 509, 513 (3rd Cir. 1995) (concluding that any state law remedy would *not* preempt injunctive relief because, in part, the state remedy is an administrative appeal process that focuses on an individual hospital's reimbursement rates, not the challenged methodology of the greater Medicaid program).

A. FAQ 33 Is a Legislative Rule That Was Promulgated Without Notice and Comment in Violation of the APA and Is Not Entitled to Deference By the Court

In both the *Texas Children's Hospital* and *New Hampshire Hospital Association* cases, the courts rejected the government's argument that FAQ 33 is an interpretative rule entitled to deference from the court. In permanently enjoining FAQ 33, Judge McCafferty found that FAQ 33 is not a regulation that is accorded deference under *Chevron, U.S.A. v. Natural Res. Def. Council, Inc.* 467 U.S. 837 (1984) (deference to agency appropriate when Congress delegated authority to promulgate regulations and the agency interpretation at issue was promulgated in the exercise of that authority). Exhibit 1, at 25. Judge McCafferty also declined to afford Defendants a lesser degree of deference under *Skidmore v. Swift & Co.,* 323 U.S. 134 (1944), which applies to agency interpretations contained in opinion letters, policy statements and similar materials like FAQs, because she found that FAQ 33 is "inconsistent with the 2008 Rule and CMS had not consistently, if ever, applied those policies to the hospital-specific DSH limit prior to issuing the FAQ[]." *Id.* at 31. In addition, she found "no evidence in the record about CMS's process by which the polic[y] set forth in . . . FAQ [33 was] considered." *Id*. at 31-32. Similarly, Judge Sullivan found in *Texas Children's Hospital*, that "[t]he formula codified by the Rule did not contemplate the inclusion of private-insurance payments for Medicaid-eligible services" and CMS "offer[s] no convincing interpretation of this regulation." 76 F. Supp. 3d at 237.

The Medicaid Act mandates that the Medicaid shortfall component of the HSL be calculated by offsetting the cost of services to Medicaid eligible individuals only with payments received from the Medicaid program. 42 U.S.C. § 1396r-4(g)(1)(A). Consistent with the Medicaid Act, the CMS regulations (duly promulgated with notice and comment) expressly provide the methodology for calculating Medicaid shortfall component of the HSL:

> The total annual uncompensated care cost equals the total cost of care for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals . . . *less the sum of regular Medicaid FFS rate payments, Medicaid managed care organization payments, [and] supplemental/enhanced Medicaid payments*[.]

42 C.F.R. § 447.299(c)(16) (emphasis added). More specifically, the CMS regulations direct that the Medicaid shortfall component of the HSL is calculated by "subtracting the amount identified in § 447.299(c)(9) [Total Medicaid IP/OP Payments] from the amount identified in § 447.299(c)(10) [Total Cost of Care for Medicaid IP/OP Services]." *Id.* § 447.299(c)(11). Total Medicaid IP/OP Payments are further delineated as (1) "Medicaid fee-for-service (FFS) basic rate payments" ("FFS Payments") (§ 447.299(c)(6)); (2) "Medicaid managed care organization payments" ("MCO Payments") (§ 447.299(c)(7)); and "Supplemental/enhanced Medicaid IP/OP payments" ("Supplemental Payments") (§ 447.299(c)(8)). The regulatory formula for calculating the Medicaid shortfall can, therefore, be expressed as:

Total cost of care for Medicaid inpatient/outpatient services	–	Total Medicaid inpatient/outpatient payments (the sum of Medicaid FFS, MCO; and Supplemental payments)[10]	=	Medicaid shortfall

The government's principal argument in the *Texas Children's Hospital* and *New Hampshire Hospital Association* cases, which both courts rejected, was that "the term 'unreimbursed costs' [in § 447.299(c)(16)] means that costs included in calculating the hospital-specific limit must be only those for which no reimbursement is received from any source." *Texas Children's Hosp.*, 76 F. Supp. 3d at 236. As Judge Sullivan explained, "[t]he phrase, however, cannot be divorced from its context—which includes a specific definition of the calculation and all relevant inputs." *Id.* at 236-37 (citing *Colautti v. Franklin,* 439 U.S. 379, 392

[10] Medicaid FFS, MCO, and Supplemental payments are all payments *made by the state* in accordance with a federally approved State Plan.

n.10 (1979) ("a definition which declares what a term means . . . excludes any meaning that is not stated") (quotation marks omitted); *Fla. Dep't of Banking & Fin. v. Bd. of Governors of Fed. Reserve Sys.*, 800 F.2d 1534, 1536 (11th Cir. 1986) ("It is an elementary precept of statutory construction that the definition of a term in the definitional section of a statute controls the construction of that term wherever it appears throughout the statute."). "It is this context that renders the defendants' argument untenable." *Id.* at 237.

Similarly, Judge McCafferty found that the "text of the 2008 Rule and other sections in the Preamble make clear that the "Rule cannot support defendants' policy and that FAQ 33 . . . [is] the sole authority for it.'" Exhibit 1, at 26-27 (quoting *Texas Children's Hosp.* 76 F. Supp. 3d at 238. Further, Judge McCafferty examined multiple sections of the Preamble, finding that it "consistently refers to the specific costs and payments that are used to calculate the Medicaid shortfall." *Id.* at 27-28. Similarly, she found that the definition of "total annual uncompensated care costs" in the 2008 Rule, "do not include payments from . . . private insurance for Medicaid-eligible patients." *Id.* at 29.

FAQ 33 *undeniably* "creates new law or imposes new rights and duties" because it, for the first time, requires that private insurance payments be included in the calculation of the DSH HSL. *Jerri's Ceramic Arts, Inc. v. Consumer Prod. Safety Comm'n*, 874 F.2d 205, 207 (4th Cir. 1989) (holding that agency statement exempting certain items from regulation was a legislative rule subject to notice and comment requirements, not a mere interpretation). Moreover, there can be no argument that FAQ 33 does not have the force and effect of law. In March 2016, CHKD sought clarification from DMAS regarding the applicability of FAQ 33 in Virginia and was told that CMS had instructed all states other than Texas, Washington, and Seattle to apply FAQ 33. Ryan Decl. at ¶ 18. CMS's direction to apply FAQ 33 in Virginia resulted in CHKD's

2013 audit identifying an overpayment of $19.1, where absent FAQ 33, the overpayment would have been $1.2 million. *Id*. ¶¶ 21-22. Similarly, after Judge Sullivan enjoined CMS from enforcing FAQ 33 in Texas and Washington, the Missouri Department of Social Services wrote to CMS asking whether it should instruct its auditor to redo the state's 2011 audit in light of the injunction. CMS responded that it was fully implementing the court's order in Texas and Washington, but "[f]or all other states, including Missouri, CMS may disallow federal financial participation if a state *does not comply with the policy articulated in FAQ No. 33*." *See* 5/1/2015 letter from CMS, attached as Exhibit 2 to Noona Decl. at 1. For these reasons, CHKD is likely to succeed on Count II of its Complaint.

B. The Policy Set Forth in FAQ 33 is Not Authorized By the Medicaid Act

"It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). When a court reviews an agency's interpretation of a statute it administers, "the question is always, simply, whether the agency has stayed within the bounds of its statutory authority." *City of Arlington, Tex. v. FCC,* 133 S.Ct. 1863, 1868 (2013). "Government action is *ultra vires* if the agency or other government entity 'is not doing the business which the sovereign has empowered him to do or he is doing it in a way which the sovereign has forbidden.'" *Ancient Coin Collectors Guild v. Dept. Homeland Security,* 698 F.3d 171, 179 (4th Cir. 2012) (quoting *Larson v. Domestic & Foreign Commerce Corp.,* 337 U.S. 682, 689 (1949)). The policy set forth in FAQ 33 is contrary to the plain language of the Medicaid Act and negates Congress's purpose for enacting the DSH program.

1. The Medicaid Act Is Unambiguous: Private Insurance Payments Are Not Included in the HSL Calculation

The Medicaid Act unambiguously specifies the "payments" that are to be included in the calculation of a hospital's HSL, *i.e.*, Medicaid payments and payments made by or on behalf of uninsured patients ("payments under this subchapter . . . and by uninsured patients."). 42 U.S.C. § 1396r-4(g)(1)(A). Private insurance payments are not included on the payment side of the statutory equation.

First, the statute unambiguously sets forth a formula for calculating the HSL and plainly distinguishes between costs and payments by giving the Secretary discretion to determine the "costs . . . of furnishing hospital services" to be included in the cost side of the equation and specifying the payments that are to be netted out of the costs ("payments under this subchapter . . . and by uninsured patients."). 42 U.S.C. § 1396r-4(g)(1)(A). The Conference Report accompanying the HSL provision explained that the HSL "[l]imits disproportionate share hospital (DSH) payment adjustments *to no more than the costs of providing inpatient and outpatient services* to Medicaid and uninsured patients, *less payments received from Medicaid* (other than DSH payment adjustments) and uninsured patients." H.R. Rep. No. 103-213, at 835 (1993) (Budget Committee Conference Report) (emphases added). The statute directs that only Medicaid payments received by hospitals be subtracted from the total costs of furnishing inpatient and outpatient hospital services to Medicaid-eligible individuals. 42 U.S.C. § 1396r-4(g)(1)(A). Nowhere did Congress indicate intent that payments received from private insurance should first be subtracted from the costs of furnishing hospital services before Medicaid payments are subtracted. As Judge McCafferty found in *New Hampshire Hospital Association*, "Congress could not have intended to grant the Secretary the discretion to include other payments within the term 'costs,' while separately defining payments. If it did, the definition of

payments that must be subtracted from costs to determine the Medicaid Shortfall would be surplusage." 2016 WL 1048023, at *12.

Second, it is a fundamental principle of statutory construction that "when Congress includes particular language in one section of a statute but omits it in another—let alone in the very next provision—th[e] Court presume[s] that Congress intended a difference in meaning," *Loughrin v. United States*, 134 S. Ct. 2384, 2390 (2014) (second alteration in original) (internal quotation marks omitted). This principle applies here with particular force because in the immediately following subsection, 1396r-4(g)(2), Congress established a formula for providing additional DSH payment adjustments to certain public hospitals for a two-year transitional period following enactment of the law. 42 U.S.C. § 1396r-4(g)(2). The formula expressly requires that the additional payment adjustment cannot

> exceed 200 percent of *the costs of furnishing hospital services described in paragraph (1)(A)* during the year but only if the Governor … certifies … that the hospital's *applicable minimum amount* is used for health services during the year [and in] determining the amount that is used for such services …, *there shall be excluded any amounts received* under the Public Health Service Act or *from third party payors* …

Id. (emphases added). The hospital's applicable minimum amount is further defined as "the difference between the amount of the hospital's payment adjustment for the fiscal year and the costs to the hospital of furnishing hospital services described in paragraph (1)(A) during the fiscal year," *i.e.*, the costs determined under (g)(1) for which no DSH funding was received. § 1396r-4(g)(2)(C). A governor had to certify that the costs (the applicable minimum amount) were used for "health services," which includes hospital services. Section (g)(2) then directs that in determining the amount that is used for "such services" (health services including hospital services), *third party payments* are excluded. If third party payments were already subtracted under (g)(1) for hospital services (a subset of health services), it would be mere surplusage for

Congress to subtract third-party payments in (g)(2), as both provisions define a formula for providing additional Medicaid funds to DSH hospitals.

Finally, the concept of "costs" is central to the overall purpose of the Medicaid Act. *Atkins v. Rivera*, 477 U.S. 154, 156 (1986) (the Medicaid program is "designed to provide medical assistance to persons whose income and resources are insufficient to meet the costs of necessary care and services."). The discretion afforded the Secretary under 42 U.S.C. § 1396r-4(g)(1)(A) is to determine which "hospital services" and their attendant costs are to be included in the DSH calculation ("the *costs* incurred during the year *of furnishing hospital services* (as determined by the Secretary . . . .)"). The Secretary has exercised this discretion on numerous occasions. For example, the Secretary determined that costs associated with rural health clinics are not allowed in the HSL calculation. *La. Dep't of Health & Hosps. v. CMS*, 346 F.3d 571 (5th Cir. 2003) (holding Secretary's decision to disallow inclusion of costs associated with services provided through rural health clinics as "hospital services" in its DSH calculation was arbitrary). Similarly, the Secretary disallowed the inclusion of the costs of some physician services in the HSL. *Va. Dep't of Med. Assistance Servs. v. Johnson*, 609 F. Supp. 2d 1, 8 (D.D.C. 2009) ("This case boils down to a dispute over the nature of the 'hospital services' that are subject to DSH reimbursement pursuant to . . . . § 1396r–4(g)(1)(A) . . . ."") (upholding Secretary's determination that certain physician's services provided to uninsured patients at two public Virginia hospitals were neither "inpatient hospital services" nor "outpatient hospital services" within the meaning of the Medicaid Act). Indeed, for example, in the audit of CHKD's 2011 DSH funds, certain transportation costs were disallowed causing CHKD to repay approximately $4.9 million of DSH funds received. Ryan Decl. ¶ 15.

2. The Policy Set Forth in FAQ 33 Negates Congress's Purpose in Enacting the Disproportionate Share Hospital Program

It is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Michigan Dept. of Treasury,* 489 U.S. 803, 809 (1989). A court must therefore interpret the statute "as a symmetrical and coherent regulatory scheme," *Gustafson v. Alloyd Co.,* 513 U.S. 561, 569, (1995), and "fit, if possible, all parts into an harmonious whole," *FTC v. Mandel Brothers, Inc.,* 359 U.S. 385, 389 (1959). "Courts cannot interpret federal statutes to negate their own stated purposes." *New York State Dept. of Social Servs. v. Dublino,* 413 U.S. 405, 419–420 (1973). Here, when the statutory formula for determining the HSL is read in the context of the Medicaid Act and with regard to Congress's stated purpose for enacting the DSH program, the policy set forth in FAQ 33 cannot be sustained.

The policy articulated in FAQ 33 that private insurance payments must be included in the calculation of the HSL defeats Congress's purpose that disproportionate share hospitals, like CHKD, receive DSH funds. Congress made clear that "[t]he purpose of the Medicaid DSH payment adjustment is to assist those facilities with high volumes of Medicaid patients in meeting the costs of providing care." H.R. Rep. No. 103-111 at 211-12 (1993), reprinted in 1993 U.S.C.C.A.N. 378, 538-39. Congress understood that when hospitals treat disproportionate numbers of Medicaid patients they incur significant losses that cannot be offset by other revenues. This is particularly true of children's hospitals, which rely principally on only two sources of revenue, Medicaid and commercial insurance. *See* Ryan Decl. ¶ 29. Unlike adult care hospitals, they are not reimbursed by Medicare. *Id.* Indeed, Congress recognized in the statute that children's hospitals are a prime example of the hospitals that should receive DSH payments

based on "the proportion of low-income and Medicaid patients . . . served by such hospitals." 42 U.S.C. § 1396r-4(a)(2)(D) ("disproportionate share hospitals, including children's hospitals").

To effectuate Congress's purpose, the statute expressly provides that hospitals are "deemed" to be DSH hospitals entitled to receive DSH payments if "the hospital's Medicaid inpatient utilization rate … is at least one standard deviation above the mean Medicaid inpatient utilization rate for hospitals receiving Medicaid payments in the State." 42 U.S.C. § 1396r-4(b)(1)(A). Other hospitals may be eligible to receive DSH funds if their MIUR is at least 1%, *id*. § 1396r-4(d)(3). Here, it is indisputable that CHKD has the highest MIUR in the state of Virginia. Ryan Decl. ¶ 5. For DSH year 2013, CHKD's MIUR was 71.21%. *Id*. at Exhibit 4 (listing DSH Year MIUR as 71.21%). But instead of reducing CHKD's financial burden as Congress intended to do, FAQ 33 recoups CHKD's $19.1 million DSH payment and denies CHKD altogether the DSH funds Congress deemed it was entitled to receive. *Id*. ¶¶ 24, 30. It does this by treating private insurance payments as if they were Medicaid payments in the HSL calculation knowing that these payments far exceed the Medicaid allowable costs and what Medicaid would have paid had the program been billed. *Id*. ¶ 30. The result is an artificial deflation of CHKD's HSL to deny CHKD DSH funds. *Id.*

That the policy set forth in FAQ 33 repudiates the purpose of the DSH program is illustrated by CHKD's 2013 data. In 2013, CHKD treated 108,347 children for whom Medicaid was the primary source of reimbursement. Ryan Decl. ¶ 31. CHKD's actual cost of the inpatient and outpatient services delivered to these children totaled approximately $131 million. *Id*. However, because Medicaid "allows" only a portion of the hospital's actual costs and only reimburses CHKD, on average, only $0.69 for every dollar it spends on treatment, Medicaid allowed only $109 million of these costs and reimbursed CHKD only $92.6 million, resulting in

an estimated actual loss to CHKD of $38.4 million. *Id.* In addition, CHKD sustained an approximate $3.4 million loss treating uninsured patients. *Id.* ¶ 9. CHKD received $19.1 million in DSH funds to, as Congress intended, partially offset its total $41.8 million loss. *Id.* Even with DSH payments CHKD sustained a loss of $22.7 million in the treatment of Medicaid and uninsured children ($41.8 million - $19.1 million). *Id.*

Yet application of FAQ 33 deems the $19.1 million DSH payment CHKD received and relied upon as an "overpayment" subject to recoupment. *Id.* ¶ 24. This is because FAQ 33 requires that the private insurance payments received for the 2,199 children ($33.7 million) offset the Medicaid shortfall ($16.4 million) CHKD incurred treating the other 108,347 children for whom Medicaid was the primary payor. *Id.* ¶ 33. The result is, and always will be, a negative HSL thereby eliminating CHKD's DSH funds altogether. *Id.* In fact, of the 2,199 patients who were covered by private insurance, it took only 36 of them to eliminate CHKD's entire $19.1 million DSH payment for 2013. *Id.*

This is not just a paper exercise. CHKD relies heavily on the revenue received from treating privately insured patients. *Id.* ¶ 29. It negotiates with each commercial payer to obtain the best contracted rates to help offset Medicaid losses and to have the funds necessary to re-invest in equipment, technology and clinical programs that enhance the lives of all patients and provide life-saving treatment for all children, including Medicaid pediatric patients treated at CHKD. *Id.* The negotiated commercial rates are necessarily higher than Medicaid allowable rates and cover services not covered by Medicaid. *Id.* ¶¶ 29, 32. While these commercial insurance payments help offset some Medicaid losses, they are not sufficient to offset all Medicaid losses and maintain operational liquidity. *Id.* ¶ 29. That is why Congress enacted the DSH program and why DSH funds are critically important to hospitals like CHKD. *Id.*

In effect, FAQ 33 robs CHKD of its private insurance revenues to further subsidize the Medicaid program by forcing CHKD to offset its large Medicaid losses with revenues received from private insurance for a small number of Medicaid eligible children at the expense of CHKD's ability to provide important hospital and community services and programs. This result simply cannot be squared with Congress's stated purpose that the DSH Program "assure that . . . [Medicaid] payment rates at a minimum meet the needs of those facilities which . . . serve a large number of Medicaid-eligible and uninsured patients who other providers view as financially undesirable." H.R. Rep. No. 100-391(I), at 524 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-344, 1987 WL 61524. Accordingly, the Court should give effect to the unambiguous intent of Congress: "costs" means the costs of providing hospital services and "payments" means Medicaid payments in determining the Medicaid shortfall. Congress did not empower Defendants to implement a policy directing that private insurance payments be included in the calculation of the HSL.

II. CHKD WILL SUFFER IMMINENT, IRREPARABLE INJURY

CHKD faces the certain and imminent harm of having to repay $19.1 million that it rightfully received in 2013 under the DSH Program with no possible recourse to recover the money. *See, e.g.*, *id.* ¶ 24. The economic losses at issue for this not-for-profit children's hospital are different in kind from the loss of corporate profits that courts have sometimes found not to be irreparable. Here, the harm is not the speculative loss of miniscule profit, but instead the imminent and material reduction of funds necessary to CHKD's mission-driven programs that provide essential clinical programs and medical services to the regional communities.

As set forth in detail in Paragraphs 35-40 of the Ryan Declaration and the Statement of Facts above, *see supra*, at 10-12, being forced to repay $19.1 million in DSH funds that were received in 2013 coupled with not receiving $8.1 million in expected DSH funds in 2017 directly

impacts CHKD's ability to continue to address current and unmet public health needs in and around its community. Ryan Decl. ¶ 36-38. CHKD is heavily investing in pediatric specialists, technology, facilities, clinical services, preventative care, supportive services, and community outreach programs all of which work towards the betterment of children within the community CHKD serves. *Id.* CHKD's ability to continue investing in these programs and services, including its ability to recruit and retain the pediatric primary care professionals and pediatric specialists essential to its patients, will be directly impacted by the loss of DSH funds. *Id.* ¶ 36. For example, $19.1 million pays the full cost of 271 Full Time Equivalent (FTE) employees, which equates to 11.7% of total hospital staffing. *Id.* ¶ 35. Courts in this circuit have issued preliminary injunctive relief upon a showing of the type of clear actual and imminent harm demonstrated here. *See e.g., United States v. South Carolina*, 720 F.3d 518, 533 (4th Cir. 2013) (affirming preliminary injunction after plaintiff made a clear showing it would likely suffer irreparable injury if the state's immigration law was not enjoined); *Direx Israel, Ltd. v. Breakthrough Med. Corp.,* 952 F.2d 802, 812 (4th Cir.1991) (for harm to be irreparable, it must be both actual and imminent).

Further, if the impending recoupment is not enjoined, CHKD will suffer irreparable harm because sovereign immunity precludes CHKD from being fully compensated through an award of damages. *See, e.g.*, *Synagro-WWT, Inc. v. Louisa Cty., VA*, No. CIV. A. 3:01CV00060, 2001 WL 868638, at *4 (W.D. Va. July 17, 2001) (finding irreparable harm, despite the calculable monetary loss, because defendant was a governmental body that enjoyed sovereign immunity and thus plaintiff's, "calculable losses" were "appropriately considered 'irreparable" and fortif[ied] its plea" for injunctive relief) (citing *Hughes Network Sys., Inc. v. InterDigital Commc'ns Corp.*, 17 F.3d 691, 694 (4th Cir. 1994) ("Even if a loss can be compensated by

money damages at judgment, however, extraordinary circumstances may give rise to the irreparable harm required for a preliminary injunction.")). *See also See Rum Creek Coal Sales, Inc., v. Caperton,* 926 F.2d 353, 361 (4th Cir.1991) (finding irreparable harm when sovereign immunity limited the remedies available to the plaintiff). Thus, once taken, CHKD will have no recourse to recover the $19.1 million even if it fully prevails on the merits of its suit.

The harms described above will be further exacerbated by the additional loss of even more DSH funds. CHKD has already been informed that its 2011 and 2012 audits will be reopened to apply FAQ 33, which will result in the misidentification of additional overpayments exceeding $32.3 million, which could also be recouped in 2017. Ryan Decl. ¶ 39. DSH funds received in 2014 through 2016 will similarly be impacted by FAQ 33 resulting in additional losses of $25.3 million. *Id*. The DSH audit for 2014 has already begun and will be concluded before December 31. *Id.* In sum, CHKD has received approximately $76.8 million dollars in DSH funding, all of which is now subject to recoupment resulting in devastating consequences to CHKD's vital mission. *Id*. ¶ 40.

III. THE BALANCE OF EQUITIES FAVORS CHKD

The court must also balance the equities. *Real Truth*, 575 F.3d at 346. Enforcement of FAQ 33 results in CHKD losing millions of dollars that it will be unable to recover, thereby jeopardizing its ability to provide vital health care programs and services to children. In contrast, there is no harm to the government because, as it has conceded elsewhere, the federal government will pay the same amount of DSH funds to any given state regardless of whether or not FAQ 33 is enforced in that state. *See* Def. Memo in Support of Motion for Summary Judgment, at 2, *Texas Children's Hosp.*, No. 14-2060 (D.D.C. filed Mar. 18, 2015) [ECF No. 25-1] ("[T]he provisions at issue in this case do not affect the total amount of DSH payments paid to hospitals in a given state; they affect only how those funds are allocated among hospitals."). "It

is thus not the case that 'the alleged irreparable economic injury suffered by . . . Plaintiff[] would be offset by the corresponding economic injury to the Secretary.'" 76 F. Supp. 3d at 246 (quoting *Allina Health Servs. v. Sebelius*, 756 F. Supp. 2d 61, 69 (D.D.C. 2010)).

IV. AN INJUNCTION IS IN THE PUBLIC INTEREST

The public interest also weighs in favor of granting preliminary injunctive relief. "[T]here is a robust public interest in safeguarding access to health care for those eligible for Medicaid, whom Congress has recognized as the most needy in the country." *Indep. Living Ctr. of S. Cal., Inc. v. Maxwell-Jolly*, 572 F.3d 644, 659 (9th Cir. 2009) (internal quotations omitted). For this reason, "[i]ssuance of an injunction to enforce the federal Medicaid Act is without question in the public interest." *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1342 (S.D. Fla. 2006) (issuing permanent injunction compelling coverage for eligible drug). "Where, as here, the plaintiff[] [is a] hospital[] that disproportionately serve[s] Medicaid-eligible patients, it is important to keep in mind that 'there is a robust public interest in safeguarding access to health care for those eligible for Medicaid, whom Congress has recognized as the most needy in the country." *Texas Children's Hosp.*, 76 F. Supp. 3d at 246 (internal quotations omitted). This is particularly true here as CHKD is the only civilian critical care facility for children in southeastern Virginia, the Eastern Shore of Virginia, and northeastern North Carolina. The loss of DSH funds directly impairs CHKD's ability to increase access to care for all children, including Medicaid children. Ryan Decl ¶¶ 2-3; 36.

The public interest is likewise served by Defendants' compliance with the law, especially given that one federal court has permanently enjoined Defendants' enforcement of FAQ 33 in one state and another court has preliminarily enjoined FAQ 33 in two other states. *See, e.g.*, *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326-27 (D.C. Cir. 1998) ("The final preliminary injunction factor, the public interest, . . . is inextricably linked with the merits of the case.").

Where "[a] statute's standards . . . were not met, then the public interest balance plainly would weigh in favor of an injunction." *Id.* at 1326. *Accord North Dakota v. EPA*, 127 F. Supp. 3d 1047, 1060 (D.N.D. 2015) ("A far broader segment of the public would benefit from the preliminary injunction because it would ensure that federal agencies do not extend their power beyond the express delegation from Congress."). Indeed, in the context of Medicare reimbursement, "the Secretary's compliance with applicable law constitutes a separate, compelling public interest." *In re Medicare Reimbursement Litig.*, 309 F. Supp. 2d 89, 99 (D.D.C. 2004). "The public interest is [also] served when administrative agencies comply with their obligations under the APA." *N. Mariana Islands v. United States*, 686 F. Supp. 2d 7, 21 (D.D.C. 2009) (preliminarily enjoining interim rule allegedly promulgated without APA compliance) (citation omitted).

CONCLUSION

For the foregoing reasons, CHKD respectfully requests that the Court enjoin Defendants from enforcing, applying, or implementing FAQ 33 or its policy that private health insurance revenues be included in the HSL calculation in Virginia. CHKD further requests that the Court order Defendants to notify the Virginia Department of Medical Assistance Services that, pending further order by the Court, CMS's enforcement of the policy set forth in FAQ 33 is enjoined and that any "overpayments" previously identified for recoupment as a result of the policy set forth in FAQ 33 are not considered "overpayments" subject for recoupment.

Dated: March 8, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 8th day of March, 2017, a true and exact copy of Plaintiff's Memorandum of Law in Support of Motion for Emergency Injunctive Relief was served via overnight delivery to:

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